UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/647,501	08/25/2003	Carl T. Allenspach	01139/3/US	2375

26648 7590 08/04/2006

PHARMACIA CORPORATION
GLOBAL PATENT DEPARTMENT
POST OFFICE BOX 1027
ST. LOUIS, MO 63006

EXAMINER	
CLAYTOR, DEIRDRE RENEE	
ART UNIT	**PAPER NUMBER**
1617	

DATE MAILED: 08/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/647,501	ALLENSPACH ET AL.	
	Examiner	Art Unit	
	Renee Claytor	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 August 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-29* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This application claims priority to Provisional Application # 60/407,212 filed on 8/30/2002 and Provisional Application # 60/479,584 filed on 6/18/2003. Applicant's priority is acknowledged.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1- 23, drawn to an orally deliverable composition comprising a drug of low water solubility and a pregelatinized starch having low viscosity and/or exhibiting a multimodal particle size distribution, classified in class 424, subclasses 456, 464 and class 514, subclass 379.

II. Claims 24-27, drawn to a process for preparing an orally deliverable pharmaceutical composition, classified in class 424, subclass 465 and class 514, subclass 379.

III. Claim 28, drawn to a method of improving drug release rate consistency among pharmaceutical tablets prepared within a single manufacturing campaign, classified in class 424, subclass 465.

IV. Claim 29, drawn to a method of treating a medical condition or disorder in a subject where treatment with a cyclooxygenase-2 inhibitor is indicated, classified in class 514, subclass 379.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the process of preparing an orally deliverable pharmaceutical composition comprising a drug of low water solubility and a pregelatinized starch having low viscosity and/or exhibiting a multimodal particle size distribution can be practiced by another materially different process such as performing different heating steps to dissolve the material or by adding different pharmaceutical additives. Because these inventions are distinct for the reasons given above and the search required for Invention I is not required for Invention II, restriction for examination purposes as indicated is proper. Moreover, the searches in non-patent literature databases would be extensive and will not overlap thus presenting a search burden to be searched together. Thus, Inventions I and II have been appropriately restricted on the basis of being both independent or distinct and presenting a search burden on the Examiner if they were to be searched together.

Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the method

of improving drug release rate consistency among pharmaceutical tablets prepared within a single manufacturing campaign can be practiced with another materially different product, namely any drug having low water solubility. Because these inventions are distinct for the reasons given above and the search required for Invention I is not required for Invention III, restriction for examination purposes as indicated is proper. Moreover, the searches in non-patent literature databases would be extensive and will not overlap thus presenting a search burden to be searched together. Thus, Inventions I and III have been appropriately restricted on the basis of being both independent or distinct and presenting a search burden on the Examiner if they were to be searched together.

Inventions I and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the method of treating a medical condition or disorder in a subject where treatment with a cyclooxygenase-2 inhibitor is indicated can be performed with another materially different product, such as aspirin or acetaminophen. Because these inventions are distinct for the reasons given above and the search required for Invention I is not required for Invention IV, restriction for examination purposes as indicated is proper. Moreover, the searches in non-patent literature databases would be extensive and will not overlap thus presenting a search burden to be searched together. Thus, Inventions

I and IV have been appropriately restricted on the basis of being both independent or distinct and presenting a search burden on the Examiner if they were to be searched together.

Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are drawn to a process for preparing an orally deliverable pharmaceutical composition and a method of improving drug release rate consistency among pharmaceutical tablets prepared within a single manufacturing campaign. The two inventions are distinct in that the method of Invention II involves the process of the preparation of a composition, while the method of Invention III involves improving drug release rate consistency among pharmaceutical tablets. Because these inventions are distinct for the reasons given above and the search required for Invention II is not required for Invention III, restriction for examination purposes as indicated is proper. Moreover, the searches in non-patent literature databases would be extensive and will not overlap thus presenting a search burden to be searched together. Thus, Inventions II and III have been appropriately restricted on the basis of being both independent or distinct and presenting a search burden on the Examiner if they were to be searched together.

Inventions II and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the

different inventions are drawn to a process for preparing an orally deliverable pharmaceutical composition and a method of treating a medical condition or disorder in a subject where treatment with a cyclooxygenase-2 inhibitor is indicated. The two inventions are distinct in that the method of Invention II involves a process for preparing a pharmaceutical composition while the method of Invention IV involves treating a medical condition or disorder. Because these inventions are distinct for the reasons given above and the search required for Invention II is not required for Invention IV, restriction for examination purposes as indicated is proper. Moreover, the searches in non-patent literature databases would be extensive and will not overlap thus presenting a search burden to be searched together. Thus, Inventions II and IV have been appropriately restricted on the basis of being both independent or distinct and presenting a search burden on the Examiner if they were to be searched together.

Inventions III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are drawn to a method of improving drug release rate consistency among pharmaceutical tables and a method of treating a medical condition or disorder. The two inventions are distinct in that the method of Invention III is improving drug release rate consistency among pharmaceutical tablets while the method of Invention IV is to treat a medical condition or disorder. Because these inventions are distinct for the reasons given above and the search required for Invention III is not required for Invention IV, restriction for examination purposes as indicated is proper. Moreover, the

searches in non-patent literature databases would be extensive and will not overlap thus presenting a search burden to be searched together. Thus, Inventions III and IV have been appropriately restricted on the basis of being both independent or distinct and presenting a search burden on the Examiner if they were to be searched together.

Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during

prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Species Election

Claims 1-29 are generic to the following disclosed patentably distinct species: drug of low water solubility, pregelatinized starch, medical condition or disorder, and cyclooxygenase-2 inhibitory drugs. Because each of the disclosed compounds are patentably distinct, each from the other, and medical conditions or disorders encompass a wide range restriction for examination purposes as indicated is proper.

In the event that Applicant elects either of Groups I, II, III or IV for further prosecution on the merits, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species of one drug of low water solubility (enumerated in claims 1 and 28; Groups I and III), one pregelatinized starch (enumerated in claims 1, 9-21, 24, and 28; Groups I, II, and III), one medical condition or disorder (enumerated in claim 29; Group IV) and one cyclooxygenase-2 inhibitory drug (enumerated in claims 3-4 and 25; Groups I and II) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held allowable. Currently claims 1, 3-4, 9-21, 24-25, and 28-29 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims

readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Conclusion to Restriction Requirement

Applicant is advised the reply to this requirement to be complete must include (i) an election of an invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Due to the complex nature of the instant restriction requirement, a written restriction requirement was necessitated. See MPEP § 812.01.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Renee Claytor whose telephone number is 571-272-8394. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Renee Claytor

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER